K021099

JUN 27 2002

Section II - Section 510(k) Premarket Notification Summary (as required by 807.92 (j))

Submitter:
PointDx, Inc.
635 West Fourth Street, Suite 200
Winston-Salem, NC 27101
Phone: 336.723.1450
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Date Prepared:
April 2, 2002

Contact Person(s):
Francis Bonk, Director of Quality Assurance and Regulatory Affairs
336-723-1450 (v)
336-723-1458 (f)

Device Trade Name:
REX™

Device Common Name:
PACS / Image Processing Software

Classification Name:
Class II – System, Image Processing, RA (90) LLZ

Substantially Equivalent To:
Rapidia® V 2.0
(K012290)
3D Med Co, Ltd.
940-319 Research Park
SNU, San 4-8
Bongcheon-dong, Gwanak-gu
Seoul 151-818
Republic of Korea

Device Description:
REX™ 1.0 is a tool for 3D (three dimensional) and 2D (two dimensional) viewing and manipulation of DICOM compliant CT images. The proposed software provides real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.

Indications for Use:
REX™ 1.0 is a software package intended for viewing and manipulating DICOM-compliant medical images acquired from CT scanners. REX™ 1.0 can be used for real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.

Technological Comparison to Predicate Device:
The proposed and predicate devices are both software programs that can be used for manipulation of DICOM-compliant CT images. The proposed and predicate software can be operated from a personal computer. REX™ 1.0 is a subset of the Rapidia® V 2.0 features with an added monitor to allow a Radiologist the convenience of using two monitors, one for image viewing, and the other for report viewing. The REX ™1.0 software has substantially equivalent features and

specifications versus the existing Rapidia® V 2.0, for those features and specifications the two devices have in common.

Non-Clinical Performance Data:
The proposed REX™ 1.0 software conforms to DICOM (Digital Imaging and Communications in Medicine) Version 3.0. Validation testing was provided that confirms that REX™ 1.0 performs all input functions, output functions, and all required actions according to the functional requirements specified in the Software Requirements Specification.

To ensure performance to specifications, Federal Regulations and User Requirements:

- Software Development Practices and
- The Validation and Verification Process

have been followed. Procedures specify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation and maintenance.

Adverse Effects on Health:
The potential hazards are identified in the Hazard Analysis and are controlled by:

- Designing controls directed at the cause and/or
- Introducing protective measures and/or
- Warning the Users.

Conclusions:
The REX™ 1.0 does not result in any new potential safety risks and performs in accordance with its intended use as well as the Rapidia® V 2.0 device currently on the market. PointDx considers features of the REX™ 1.0 to be substantially equivalent to the subset of features in common with Rapidia® V 2.0 (K012290) device.

Substantial Equivalence Chart

Tabular Comparison of Features and Specifications of the REX™ 1.0 and the Rapidia® V2.0

System	REX™	Rapidia®
Version	**1.0**	**2.0**
Manufacturer	PointDx, Inc.	3D Med Co., Ltd.
510(k) Number	-	K012290
Classification	Class II 892.2050 90 LLZ	Class II 892.2050 90 LLZ
Intended Use	REX™ 1.0 is a software package intended for viewing and manipulating DICOM-compliant medical images acquired from CT scanners. REX™ 1.0 can be used for real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.	Rapidia® is a software package intended for viewing and manipulating DICOM-compliant medical images from CT and MR scanners. Rapidia® can be used for real-time viewing, image manipulation, segmentation, 3D volume and surface rendering, virtual endoscopy, and issuing reports.
Graphical User Interface	Yes	Yes
Platform		
PC	Yes	Yes
Operating System		
Windows 2000	Yes	Yes
Windows XP	No	Yes
Windows NT	No	Yes
Image Display Monitor	1	1
Report Display Monitor	1	Unspecified
Patient Demographics	Yes	Yes
Networking		
TCP/IP	Yes	Yes
Image Communication		
DICOM 3.0 compliant	Yes	Yes
Image Compression		
PNG (Lossless)	Yes	Unspecified
Image Processing		
Annotations – marker	Yes	Yes
3D Image Processing		
Volume rendering	Yes	Yes
Image Review		
Still	Yes	Yes
Window	Yes	Yes
Level	Yes	Yes
Zoom	Yes	Yes
Pan	Yes	Yes
Flip	Yes	Yes
2D Measurements		
Length	Yes	Yes
Area	Yes	Yes

System	REX™	Rapidia®
Image Source		
CT	Yes	Yes
MR	No	Yes
Image Input		
DICOM 3.0	Yes	Yes
Image Output	PNG (lossless snapshots)	JPEG, BMP, DICOM
Use Standard Monitor	Yes	Yes
Patient and Study Browser	Yes	Yes
Multi Planer Reformatting	No	Yes
Measure CT Numbers		
ROI	Yes	Yes
Type of Software		
Standalone	Yes	Yes
Virtual Endoscopy		
Instant access to lesions by single click	Yes	Yes
Real time display of endoscopic view	Yes	Yes
Internal and external viewing of any hollow structures	Yes	Yes
Fly-through	No	Yes
Real time interactive correlation among 3D image, endoscopic image and MPR images with respect to the point of view, viewing area and lesion localization	No	Yes
Display multiple objects in different color and opacity	No	Yes
Local Image Storage	Yes	Yes
True Color	Yes	Yes
User Login	Yes	Unspecified
Preset Window and Level	Yes	Yes
Image Conversion	Yes (for viewing in browser)	Yes
Device Users		
Trained Physicians	Yes	Yes
Compliance Standards		
DICOM 3.0	Yes	Yes
Algorithms		
Volume Rendering	Yes	Yes
Reporting	Yes	Yes
Physical Characteristics	• Software Package • Operates on off-the-shelf hardware (multiple vendors) • Windows 2000 operating system • DICOM compatible	• Software Package • Operates on off-the-shelf hardware (multiple vendors) • Windows 2000, XP, or NT operating system • DICOM compatible
Safety	• Clinician interactive review/editing of data integral to use of tool	• Unspecified

Table 1. Substantial Equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2002

Mr. Robert Anderson
Chief Operating Officer
PointDX, Inc.
635 West Fourth Street, Suite 200
WINSTON-SALEM NC 27101

Re: K021099
Trade/Device Name: REX™ 1.0 PACS / Image Processing Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 3, 2002
Received: April 4, 2002

Dear Mr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K K021099

Device Name: REX™ 1.0 PACS / Image Processing Software

INDICATIONS FOR USE:

Intended Use:

Indications for Use:

REX™ 1.0 is a software package intended for viewing and manipulating DICOM-compliant medical images acquired from CT scanners. REX™ 1.0 can be used for real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use)_____
Per 21 CFR 801.109

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021099